REMARKS

Claims 28-32, 34-38 and 42-47 are pending. Claims 28-30, 32, 34, 42, 43, 44 and 47 are newly amended to more clearly define Applicant's claimed invention.

No new matter has been entered.

Drawings/Specification

Applicant has provided schematic diagrams of originally filed Figures 1A and B..

Claim Objections and Rejections

Claims 28-32, 34-38 and 42 are is objected to because of the following informalities: the claims interchange the term "the vaginal specimen" and "the specimen". Accordingly, Applicant has amended the recitations of "the specimen" to recite "the vaginal specimen" or "said vaginal specimen" in the instant claims.

Claims 42 and 43 are objected to because of the following informalities: the office action contends that the recitation of "a brush attached to said inner tube with a longitudinal axis and bristles" should apparently read "a brush attached to said inner tube, having a longitudinal axis, and bristles", "a brush having a longitudinal axis, attached to said inner tube, and bristles", or the like, to avoid indefiniteness issues with respect to depending claims 35 and 44. Accordingly, Applicant has amended the recitation of "a brush attached to said inner tube with a longitudinal axis and bristles" to recite "a brush attached to said inner tube, having a longitudinal axis, and bristles".

Claim 43 is objected to because of the following informalities: the recitation in line 3 of "(a)" should apparently be deleted since the "(b)" was deleted. Accordingly, Applicant has amended claim 43 to delete "b".

Claim 47 is objected to because of the following informalities: the office action contends that the recitation in line 2 of "the sample" should apparently read "the vaginal specimen".

Accordingly, Applicant has amended the recitations of "the sample" to recite "the vaginal sample".

Claim Rejections – 35 USC § 112-2nd paragraph

Claims 28-32, 34-38, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically the office action contends:

Independent claim 42, from which claims 28-32 and 34-38 depend, positively recites in the last two lines "detecting the presence of HPV in the specimen without requiring that the specimen contains endothelial cells". Claim 42 also requires that the vaginal specimen contains cervical epithelial cells and few or no endocervical cells.

Applicant has amended claim 42 to specify that detecting the presence of HPV in the specimen does not require that it contains endocervical cells as opposed to the former recitation of endothelial cells. The term "endocervical" is an art recognized term and is defined as "pertaining to the interior of the cervix"; Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier. Applicant also has removed from claim 42 and 43 the recitation that specifies that the vaginal specimen contains cervical epithelial cells. Thus, the sample encompassed by the instantly claimed method is a vaginal sample that contains few or no endocervical cells.

Claim Rejections – 35 USC § 102

Claims 34-38 and 42-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Wallach (US 2002/0120213 Al).

Applicant respectfully traverses.

The cells targeted for sampling differ in the method for collecting a specimen useful for detecting the presence of human papilloma virus (HPV) taught by Wallach vs. the instantly claimed method. Wallach teaches "a device for self-sampling to obtain a sample of cells from the cervix to be tested for HPV DNA", see the Summary of Wallach (paragraph 0011 US 2002/0120213 Al). Wallach include in its background section that "studies have shown that

testing of samples of cervical cells for human papillomavirus (HPV) DNA can be used to screen for cervical disease", Wallach (paragraph 0004 US 2002/0120213 Al)

Wallach teaches:

> "After the sampling device is fully inserted within the vaginal cavity and the distal end of the insertion shield is located proximate to the cervix, the insertion shield is at least partially withdrawn, exposing the mop-like brush of the device to the cervix. The exposed mop-like brush is then rotated by the handle to obtain a sample of cells from the epithelium layer of the cervix adhering to the mop-like bristles of the brush. Due to the design of the mop-like brush, a representative sample of cells can be obtained without the need to locate the sampling device in an exact location relative to the cervix. After the sample has been collected, the handle is used to pull the mop-like portion back into the insertion shield and the sampling device is removed from the vagina. The mop-like brush containing the cell sample can then be tested to determine the presence of HPV DNA," emphasis added, Wallach (paragraph 0012 US 2002/0120213 Al).

Instead of sampling for cervical cells as taught by Wallach, Applicant has taken a distinctly separate method of screening for cervical disease based on the findings that endocervical cells are not required for detecting HPV in a cervical/vaginal specimen, see paragraph 0018 of the instant specification. The term "endocervical" is an art recognized term and is defined as "pertaining to the interior of the cervix"; Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier.

Because Applicant has disclosed that endocervical cells are not required for detecting HPV in a vaginal specimen, Applicant has developed the instantly claimed method for obtaining a vaginal sample using a device Applicant developed that designed to sample the lateral walls of the vagina. Thus, the device as recited in the instant claims comprises a brush attached to an inner tube, and an outer tube that serves as shield to the brush and the inner tube. The brush includes a longitudinal axis that runs through the inner tube and bristles that extend laterally outward and substantially perpendicular from the longitudinal axis.

As depicted in the instant specification:

> "As shown in FIGS. 1A and 1B, the device comprises a brush attached to an inner tube, and an outer tube that serves as shield to the brush and the inner tube. The brush includes a longitudinal axis that runs through the inner tube and bristles that

> extend laterally outward from the longitudinal axis. The brush and the inner tube as a whole are called the collection element", paragraph 0020 of the published application, and
>
> "In the self-sampling method described herein, one preferred embodiment comprises inserting the collection device into the vagina, protruding the collection element out to have the bristles contact with the cervical/vaginal tissues, rotating the inner tube of the collection element, withdrawing the collection element back into the shield, and taking the whole collection device out of the body. The bristles containing the vaginal sample is then immersed into a liquid collection medium", paragraph 0022 of the published instant application.

The bristles of the device taught by Wallach et al are "connected to a handle to form a mop-like sample collecting member, said bristles being disposed in a direction substantially parallel to the axis of the handle", as described above. In other words, the bristles are at the tip of the device as illustrated in Figures 1-5, and extend parallel to the longitudinal axis of the brush, in order to expose the mop-like brush to the cervix, allowing for its use in obtaining a sample of cervical cells on the bristles. These are shown in the attached Figure 2 of the Wallach patent, shown below.

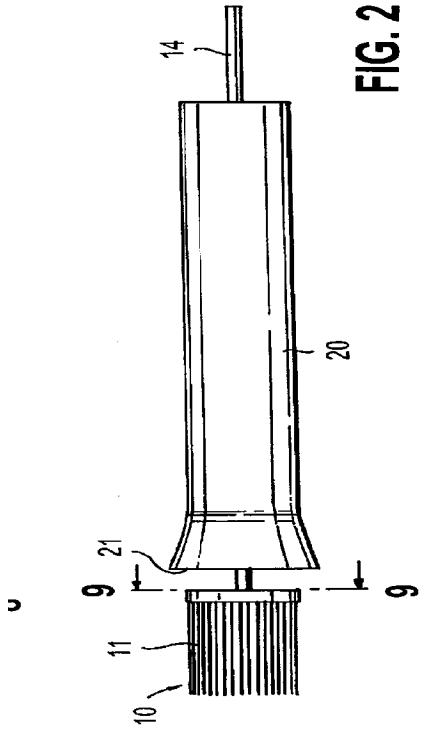
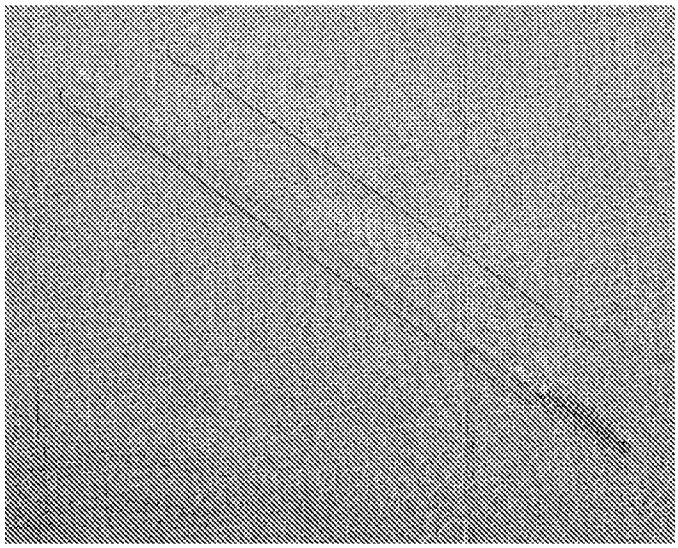
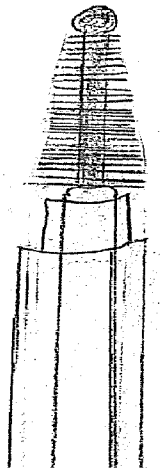


FIG. 2

In contrast, the bristles used in the instantly claimed method are perpendicular to the longitudinal axis of the brush as shown in the following figures. The difference in the direction of the bristles yields a difference in the cells being sampled; cervical versus vaginal cells.





Anticipation requires that the purported prior art reference disclose each and every limitation of the claims. *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). Applicant contends that Wallach does not teach each and every limitation of the instant claims as newly amended.

The device of the instantly claimed method is structurally different from the device of taught in the methods of Wallach. In Wallach, the bristles are substantially parallel, not substantially perpendicular, to the length of the axis as required by the instant claims for sampling the lateral sides of the vagina. The bristles taught by Wallach are located at the tip of the axis rather than on the side of the brush, and as such are clearly not positioned in a direction that is perpendicular to the axis, and are designed to obtain cervical cells by "mopping" in the area of the cervix. Thus, different cells are sampled.

Thus, in addition to the structural differences between the instantly recited device and the referenced device, the cell sample obtained by the instantly claimed device differs from that obtained by the referenced device in a method of detecting HPV..

As noted by the Examiner, Wallach is expressly concerned with gathering the cells from the epithelium layer of the cervix via self-collection by the patient, (see paragraph 12). In contrast, the cell sample obtained in the method of the instant claims is not directed to the epithelium layer of the cervix, but instead is directed to the vaginal walls.

Thus, the device used in the method of Wallach and the device used in the present method are entirely different. Consequently, the cellular component of the samples collected in the method using the device taught by Wallach is different from the cellular component of the samples collected using the device recited in the instantly claimed method. Because the instantly claimed methods for detecting the presence of a human papilloma virus require the use of a device that is structurally distinct from the device used in the methods taught by Wallach, resulting in a different cellular population obtained for HPV analysis, the teachings of Wallach are not anticipatory.

The Examier further indicates that with respect to "the longitudinal axis" of the brush and/or inner tube as claimed, "the longitudinal axis" is not required and/or defined to be along a

direction of insertion of the collection element into the patient or even along the length of the brush, inner tube, collection element, and/or device along a direction of insertion of the collection element into the patient or even along the length of the brush, inner tube, collection element, and/or device. Accordingly, Applicant has amended the claims to more clearly describe the device in Figure 1.

In view of the claim amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the instant rejection.

Claims Rejections – 35 USC § 103

Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallach in view of Zavada et al (US 2003/0049828 Al, hereinafter Zavada).

Applicants respectfully traverse on the grounds that neither Wallach alone, nor when combined with Zavada, teach all the limitations of the instant claims as newly amended. Applicants submit that for a determination of obviousness to be proper, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

As discussed in the rebuttal to the 102 rejection, Wallach does not teach a method for detecting HPV in a vaginal specimen comprising the use of a specimen collection device where a brush contains bristles that are perpendicular to the inner tube of the collection device, as required by the instant claims. Nor does Wallach teach a method designed to obtain a vaginal sample without requiring that the specimen contains cervical endothelial cell.

Zavada et al.'s teaching of methods comprising assaying bodily fluids for the presence of MN proteins using antibodies and proteins does not make up for Wallach 's not teaching the recited structural device nor a method designed to a sample that does not require obtain cervical endothelial cells, as required by the instant claims.

Therefore, Applicants contend that the teachings of Wallach, either alone or in combination with Zavada et al., do not teach all the limitations of the instant claims. Specifically

the limitations that the instantly recited device comprise a collection element with a retractable inner tube, and a brush attached to the inner tube with a longitudinal axis and bristles that are substantially perpendicular to the longitudinal axis of the brush, is not taught or suggested by either Zavada et al. nor Wallach., either individually or when combined. In contrast, the design of the device taught by Wallach reflects the goal of obtaining cervical cells in Wallach's method of detecting HPV, while the design of the device recited in the instant claims reflects the goal of obtaining cells from the vaginal walls with no requirement that the sample contain cervical endothelial cells.

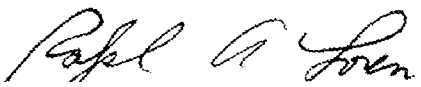
In view of the distinct structural and functional features of the instantly recited device from that taught in the references cited in the Office Action, Applicants contend the instant claims are not anticipated nor made obvious by the cited references.

Conclusion

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Dated: February 12, 2010

Respectfully submitted,



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